

## REMARKS

This is a supplemental response to the final Office Action mailed December 31, 2007, the Advisory Action mailed March 19, 2008, and the Examiner interview of March 25, 2008. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

In the Advisory Action, the Examiner maintains the previous rejections. Applicants thank the Examiner for extending the courtesy of a telephone interview to Applicants undersigned representative on March 25, 2008.

### *Amendments to the Claims*

As suggested by the Examiner in the Advisory Action, Applicants amend independent claims 1 and 19 to recite that the nonwoven polymeric material has a density in the range of about 120 mg/cc to 360 mg/cc. Support for these amendments can be found throughout the specification, for example, at Par. 0048 of the published application. Claim 34 is cancelled. Applicants also amend independent claim 19 to include the features recited in claim 22. Claim 22 is cancelled. No new matter is added.

### *Rejections Pursuant to 35 U.S.C. §112*

The Examiner rejects claims 1-8, 10-14, 16-27, and 32-34 under 35 U.S.C. §112, second paragraph, as being indefinite. In the Advisory Action, the Examiner asserts that “Applicant’s amendment does not limit the upper end of the disclosed range and as such, the scope of the range, as claimed, far exceeds the range set forth in the specification. This constitutes new matter.” The Examiner also states that “the rejection under 35 USC 112, second paragraph would be overcome if Applicant were to recite the density range as stated in paragraph 48 of the patent application.” As noted above, Applicants amend claims 1 and 19 to recite that the nonwoven polymeric material has a density in the range of about 120 mg/cc to 360 mg/cc, thereby obviating the basis for the Examiner’s rejection.

### *Rejections Pursuant to 35 U.S.C. §103*

The Examiner rejects claims 1-8, 10-14, 16-27, and 32-34 pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. US 2002/0127265 of

Bowman et al. ("Bowman"), in view of WO 01/85226 of Huckle et al. ("Huckle"), and exemplified by Boland et. al., (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243) ("Boland"). Applicants continue to respectfully disagree with the Examiner's rejection.

Claims 1 and 19 each recite, in part, that the scaffold includes a "nonwoven polymeric material having a density in the range of about 120 mg/cc to 360 mg/cc." Bowman discloses "a mesh reinforcing material." (Bowman at Par. 0066). In the Advisory Action, the Examiner argues that "although Bowman does not recite the density of their nonwoven scaffolds in units of mg/cc, [Bowman] provides sufficient evidence that such a density is a testable physical property." However, the method of density evaluation disclosed by Bowman relates only to the evaluation of the density of mesh materials, not nonwoven polymeric materials as claimed. Although the Examiner discusses the methods of measuring mesh density disclosed by Bowman, Applicants submit that the Examiner has not made out a *prima facie* case of equivalence. (See MPEP 2183). In particular, the Examiner has failed to provide an explanation and rationale as to why the mesh material disclosed by Bowman is an equivalent of the nonwoven polymeric material of the instant invention. Moreover, the Examiner has failed to provide an explanation and rationale as to why the *density* of Bowman's mesh would be equivalent to the claimed nonwoven polymeric material *density*. The mere fact that the density of Bowman's mesh "is a testable physical property" does not support the contention that Bowman's mesh is equivalent to the claimed nonwoven polymeric material or that the density of Bowman's mesh would be equivalent to the density of the claimed nonwoven polymeric material. Indeed, Applicants disclose that "[t]he term 'nonwoven' as used in the present invention, and as understood by one skilled in the art, *does not include woven, knit, or mesh fabrics*." (See Published Application at Par. 0048, emphasis added). Furthermore, Bowman discloses that a "low density, or open knitted mesh material, is preferred." (See Bowman at Par. 0066). Thus, not only does the instant specification suggest that Bowman's mesh is not equivalent to the claimed nonwoven polymeric material, the teachings of Bowman also tend to show nonequivalence. (See MPEP 2184). Finally, Bowman also fails to teach or suggest that the mesh material has a density in the claimed range.

Claims 1 and 19 also recite that the scaffold has an initial modulus of elasticity greater than about 1.5 MPa. Bowman does not teach or suggest a scaffold having the claimed

modulus of elasticity. Indeed, in the previous Office Action dated May 4, 2007, the Examiner admitted that Bowman "does not explicitly teach the specific modulus of elasticity...of the claimed scaffold."

In the Advisory Action mailed March 19, 2008, the Examiner relies on the disclosure of Bowman at paragraph 0031 to argue that "because the modulus of elasticity is the ratio of stress to strain, the '265 publication provides sufficient evidence to suggest that, absent evidence to the contrary, the scaffolds taught therein will have a modulus of elasticity greater than about 1.5 MPa, based on the stress and strain requirements set forth in [Bowman]." This is incorrect. As discussed with the Examiner during the March 25, 2008 telephone conference, Bowman does not set forth any strain requirements. Paragraph 0031 of Bowman discloses "suitable elastomers exhibit a high percent elongation and a low modulus, while possessing good tensile strength and good recovery characteristics." Although paragraph 0031 also discloses that "suitable elastomers should also have a tensile strength greater than about 500 psi, preferably greater than about 1,000 psi, and a tear strength of greater than about 50 lbs/inch, preferably greater than about 80 lbs/inch," there is no disclosure of a strain requirement. Furthermore, the disclosed values of tensile strength and tear strength are insufficient to determine a modulus of elasticity. Modulus of elasticity is the ratio of stress to strain. (*See* "Machinery's Handbook," Green, 25<sup>th</sup> edition, Industrial Press Inc., 1996, pages 192-193, copies enclosed). Therefore, a determination of the modulus of elasticity can only be made if a value of strain is known. Strain is a dimensionless quantity defined as "the amount by which a dimension of a body changes when the body is subjected to a load, divided by the original value of the dimension." (*Id.*). None of the values provided by Bowman in paragraph 30 are a strain or can be used to calculate a modulus of elasticity. Thus, Bowman fails to provide any evidence to suggest that the elastomers taught therein will have a modulus of elasticity greater than about 1.5 MPa as required by claims 1 and 19. Indeed, paragraph 31 mentions a "low modulus" in the context of a material with a high percent elongation and good recovery characteristics, properties that indicate the elastomers disclosed by Bowman have good characteristics when stretched and are relatively flexible. Paragraph 31 therefore suggests, if anything, that the modulus of elasticity of the elastomers disclosed by Bowman would be lower than the claimed range.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claim 34 is cancelled, thereby obviating the

Examiners rejection thereto. Claims 2-8, 10-14, 16-18, 20-27, and 32-33, which depend from claims 1 and 19, distinguish over the cited art at least because they depend from an allowable base claim.

***Obviousness-Type Double Patenting Rejections***

The Examiner has provisionally rejected claims 1-8, 10-14, 16-27, and 32-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477.

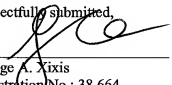
Applicants believe that all pending claims are allowable. As the instant application was filed earlier than the application that forms the basis of the non-statutory double patenting rejection, the Examiner should withdraw the provisional rejection and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

***Conclusion***

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

Dated: *May 15, 2008*

Respectfully submitted,

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